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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Petra Cirpus

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EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT

PAPER NUMBER

1638

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/511,621	<b>Applicant(s)</b> CIRPUS ET AL.	
	<b>Examiner</b> Elizabeth F. McElwain	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The amendment filed April 24, 2008 has been entered.

Claims 1, 4, 12 and 18-20 are currently amended.

Claims 21 and 22 are newly submitted.

Claims 2 and 3 are cancelled.

Claims 1 and 4-22 are pending and are examined on the merits.

### ***Election/Restrictions***

1. Applicants pointed out that the election was made with traverse, and that it was a provisional election to saturated C2-C24-alkylcarbonyl. In addition, since it is an election of species requirement, the claims will be amended when allowable subject matter is indicated. The Examiner regrets the error. However, the Examiner maintains that it remains a burden to search and examination all of the species that are claimed.
2. Applicant's election of R1 as general formula II; R2 as unsaturated C2-C4-alkylcarbonyl; and R3 as unsaturated C2-C4-alkylcarbonyl in the reply filed on November 2, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

***Claim Rejections - 35 USC § 112***

The rejections of the claims under 35 112-2<sup>nd</sup> paragraph are withdrawn in view of the amendment of the claims.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1 and 4-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process of producing in a tobacco plant transformed with the delta-6 elongase of SEQ ID NO: 3, the delta-6 desaturase of SEQ ID NO: 13 and the delta-5 desaturase of SEQ ID NO: 20 the compound represented by 20:3-9765 and 20:4-9938 in Figure 2, does not reasonably provide enablement for the claimed process of producing any and all of the compounds recited in claim 1 having any of C2 to C24 alkylcarbonyl groups as R2 and R3 and by transformation of any plant species with any set of three nucleic acids that may encode a polypeptide having as little as 90% identity with any of the recited amino acid sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims for the reasons set forth in the last office action.
5. Applicants' arguments filed April 24, 2008 have been fully considered but they are not persuasive. Applicants argue that the specification provides several examples of constructs comprising multiple desaturases/elongases and examples of said genes by Genbank Accession

number. Applicant asserts that the specification exemplifies both tobacco and linseed plants transformed with a three gene construct, pointing to page 53, lines 12-17. In addition, applicants point to the post filing date publication of Abbadi et al, stating that the results presented provide support for the production of two C20 fatty acids in tobacco and four C20 fatty acids in linseed. Applicants argue that the post filing date publication of Abbadi et al also provides guidance for identifying, isolating and analyzing homologs of genes of the invention.

6. The Examiner maintains that while the specification discloses a number of nucleic acid sequences that may be used in the invention, the specification only discloses a tobacco plant transformed with the delta-6 elongase of SEQ ID NO: 3, the delta-6 desaturase of SEQ ID NO: 13 and the delta-5 desaturase of SEQ ID NO: 20 the compound represented by 20:3-9765 and 20:4-9938 in Figure 2. Applicant has argued that transformed linseed has also been exemplified. However, the Examiner maintains that Figure 2 is labelled "Fatty acid profile of transgenic of transgenic tobacco seeds". Figure 3 only provides data for tobacco control plants. There is no way to discern from the data provided that linseed plants are also being analyzed, or how one would determine which peaks relate to tobacco, and which to linseed. With regard to Abbadi et al, this is a post-filing date publication, and it is unclear how the constructs and methods relate to those that are disclosed in the specification.

7. Applicants further argue the references cited in the rejection, asserting that Doerks, Brenner, Bork and Smith all teach that some of the time sequence homology does relate to function. Applicants also assert that Broun et al teach which amino acid substitutions can and cannot be made that will effect enzyme activity. The Examiner maintains that these references were relied upon as evidence that one cannot rely on sequence homology alone to determine the

function of a nucleic acid or an amino acid sequence. And with regard to the Broun et al reference, they teach which amino acid substitutions can be made in a delta-**12** desaturase. However, Broun et al do not teach essential amino acids or structure for delta-**6** desaturases, delta-**5** desaturases, or for delta-**6** elongases.

8. Applicants further argue that screening and testing for fatty acid modification in microorganisms and in plant species would be routine. The Examiner maintains that the claims are drawn to a process of producing compounds in plants, and that the specification provides only one limited working example in tobacco for one gene construct, while the claims are drawn to a multitude of possible gene constructs that may or may not comprise a delta-5 desaturase, and for use in any plant species. The Examiner maintains that it would require undue experimentation by one skilled in the art to make and/or use the invention, as broadly claimed.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EFM

/Elizabeth F. McElwain/  
Primary Examiner, Art Unit 1638